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IN THE

Supreme Court of the United States

OCTOBER TERM, 1992

GOOD SAMARITAN HOSPITAL, *et al.*,
Petitioners,

v.

LOUIS W. SULLIVAN, M.D.,
SECRETARY OF HEALTH AND HUMAN SERVICES,
Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Eighth Circuit

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BRIEF OF THE AMERICAN HEALTH CARE ASSOCIATION AS *AMICUS CURIAE* ON BEHALF OF PETITIONERS

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BRIEF OF THE AMERICAN HEALTH CARE ASSOCIATION AS *AMICUS CURIAE* ON BEHALF OF PETITIONERS

INTEREST OF *AMICUS CURIAE*

Amicus curiae American Health Care Association ("AHCA") is the largest national trade association representing the long term care (nursing home) industry. AHCA is a private, voluntary, nonprofit federation of 51 affiliated State associations representing more than 11,000 non-profit and proprietary long term care providers that care for over 1.1 million nursing home residents. As such, AHCA represents about two-thirds of the nation's 16,000 nursing homes, many of which provide skilled nursing facility ("SNF") services to eligible beneficiaries under the federal Medicare program.

Assuring high quality SNF services requires the hard work and cooperation of many dedicated health care professionals and non-professional staff. Further, the experience of AHCA's members has shown that there is a vital link between the ability of nursing homes to provide such care and the adequacy of the payment rates they receive.

Like the petitioner hospitals during the cost periods at issue in this case, nursing homes that participate in Medicare as SNFs receive reimbursement for the lesser of their "reasonable cost" of providing SNF services to Medicare patients or their "customary charges" with respect to such services. 42 U.S.C. § 1395f(b)(1) (1988 & Supp. 1990). While this "reasonable cost" reimbursement has now been replaced for most hospitals by a prospective payment system, SNFs continue to be reimbursed on a "reasonable cost" basis. AHCA's interest in this case is its concern that individual nursing homes preserve their ability to secure "reasonable cost" reimbursement—through retroactive corrective adjustments under 42 U.S.C. § 1395x(v)(1)(A)(ii)—which accounts for the true, necessary costs of SNF services to Medicare

patients, even where the Secretary's substantive regulatory reimbursement methods do not pay the reasonable cost of those services.[1]

BACKGROUND ON THE MEDICARE PROGRAM AND REASONABLE COST REIMBURSEMENT OF SNFS

A. The Medicare Program

The Medicare program provides a nationwide, federally-funded health insurance program for the elderly. The Secretary of Health and Human Services ("Secretary") has delegated authority to administer the Medicare program to the Health Care Financing Administration ("HCFA"). The program consists of two parts, Part A and Part B, each of which has separate rules, requirements, and funding mechanisms. Medicare Part A, the Hospital Insurance Program at issue in this case, pays for inpatient hospital, SNF, home health, hospice, and certain dialysis services through mandatory taxes on workers' wages. 42 U.S.C. §§ 1395d(a), 1395i, 1395rr(a) (1988 & Supp. 1990).

Medicare Part A covers up to 100 days of SNF services per spell of illness, following a prior hospitalization. *Id.* §§ 1395d(a)(2), 1395x(i) (1988 & Supp. 1990). In order to be reimbursed for such services, however, a nursing home must meet a variety of "participation requirements" and be certified as a SNF. *See id.* § 1395i-3(g) (1988 & Supp. 1990). As part of the Omnibus Budget Reconciliation Act of 1987 ("OBRA 1987"), Congress enacted a comprehensive series of nursing home reforms to these participation requirements, which are equally applicable to the Medicaid program.[2] Most of

[1] Pursuant to Rule 37.3 of the Rules of this Court, the parties have consented to the filing of this brief. The parties' letters of consent have been filed with the Clerk of the Court.

[2] The Medicaid program is a joint federal-state welfare program authorized under Title XIX of the Social Security Act to provide medical care for the indigent. *See* 42 U.S.C. § 1396 *et seq.* (1988 & Supp. 1990). Under Medicaid, states become eligible for federal matching funds by submitting a "state plan" to the Secretary which conforms to federal requirements. Medicaid covers "nursing facility" ("NF") care, which includes care of individuals whose medical needs are not acute enough to qualify for Medicare SNF benefits or whose needs are equally acute but who do not qualify for Medicare SNF benefits on other grounds. *Id.* §§ 1396d(a)(4), 1396(f), 1396r (1988 & Supp. 1990).

these reforms became effective October 1, 1990. OBRA 1987, § 4204(a), P.L. 100-203, 101 Stat. 1330, 1330-182. On a general level, OBRA 1987 requires a SNF to "provide services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident . . . ." 42 U.S.C. § 1395i-3(b)(2) (1988). Among the more specific OBRA 1987 provisions are requirements relating to individualized assessments, reviews, and plans of care for each resident; minimum nurse staffing standards; training, testing, and continuing education of nurse aides; provision of social services; and management of residents' personal funds. *See id.* §§ 1395i-3(b)-(c) (1988 & Supp. 1990).

B. Medicare Reimbursement Of SNFs

Medicare pays SNFs (as it did the petitioner hospitals in the cost years under appeal) an amount equal to the lesser of their "reasonable costs" for SNF services or their "customary charges" for such services. 42 U.S.C. § 1395f(b)(1). This system is generally referred to as the "reasonable cost" methodology. Under this system, which remains in effect for SNFs,[3] providers of services file annual cost reports which are then audited by the Secretary's agents (commonly known as "fiscal intermediaries") to determine, on a *retrospective* basis, whether the costs that were actually incurred were "reasonable." *Id.* at §§ 1320a, 1395h (1988 & Supp. 1990).

The Medicare statute defines "reasonable cost" as "the cost actually incurred, excluding therefrom any part of incurred cost found to be unnecessary in the efficient

[3] As noted earlier, Medicare no longer reimburses most hospitals on a "reasonable cost" basis. Instead, Medicare now generally pays for inpatient hospital services using a "prospective payment" methodology. *See id.* § 1395ww (1988 & Supp. 1990).

delivery of needed health services . . . ." *Id.* § 1395x (v)(1)(A) (1988). The statute further provides that reasonable costs "shall be determined in accordance with regulations establishing the method or methods to be used, and the items to be included, in determining such costs." *Id.* The methods of reimbursement *may*: (1) allow for the determination of costs on a per diem, per unit, per capita, or other basis; (2) take into account differing circumstances; (3) use estimates of costs of particular items and services; (4) establish cost limits on overall costs or costs of specific items; and (5) base reimbursement on a provider's charges. *Id.* On the other hand, the reasonable cost regulations *must*:

> (i) take into account both direct and indirect costs of providers of services . . . in order that, under the methods of determining costs, the necessary costs of efficiently delivering covered services to individuals covered by insurance programs established by this title will not be borne by individuals not so covered and the costs with respect to individuals not so covered will not be borne by such insurance programs, and (ii) provide for the making of suitable retroactive corrective adjustments where, for a provider of services for any fiscal period, the aggregate reimbursement produced by the methods of determining costs proves to be either inadequate or excessive.

Id. In the SNF context, the reimbursement methods must also take into account, in a manner consistent with the above provisions, the per-diem costs to SNFs of complying with OBRA 1987's nursing home reforms. *Id.* § 1395x(v)(1)(E) (1988 & Supp. 1990).

The Secretary's regulations governing reasonable cost reimbursement appear at 42 C.F.R. § 413.1 *et seq.* Among other things, those regulations include the "methods" for (1) defining what types of costs are "allowable" for reimbursement, (2) allocating direct and indirect costs among the various operational functions of a provider ("cost finding"), and (3) apportioning a provider's total allowable costs among its Medicare and non-Medicare patients ("cost apportionment"). *See* 42 C.F.R. §§ 413.24, 413.53, 413.80 *et seq.* (1991). The Secretary's regulations do not provide an explicit mechanism for making retroactive corrective adjustments to reimbursement where these methods produce substantively inadequate reimbursement.

In addition to the general authority under 42 U.S.C. § 1395x(v)(1)(A), the Medicare statute contains additional authority for using prospective cost limits (*i.e.*, limits developed in advance of the rate period) for SNFs. Specifically, 42 U.S.C. § 1395yy requires the Secretary to recognize a SNF's "routine service costs" as reasonable only if they fall within specified percentages of the mean routine service costs for comparable SNFs. These "routine cost limits" must take into account geographical wage differences, must be updated periodically, and may be adjusted for a particular SNF based upon the acuity levels of its patients or "circumstances beyond the control of the facility." 42 U.S.C. § 1395yy(a)-(c) (1988 & Supp. 1990).[4]

The Secretary has invoked the authorities described above to promulgate "cost limits" applicable to SNFs, similar to the hospital cost limits challenged by petitioners below. Both hospitals and SNFs may request "exemptions" from or "exceptions" to (*i.e.*, upward revision of) the cost limits. 42 C.F.R. § 413.30(e) (1991). The SNF exemptions and exceptions are fewer in number than those available for hospitals, however. Whereas a hospital may seek an exemption as a sole community provider, new provider, or rural provider with less than 50 beds, a SNF may only obtain an exemption if it meets the

[4] When 42 U.S.C. § 1395yy was enacted as Section 2319 of the Deficit Reduction Act of 1984, P.L. 98-369, 98 Stat. 494, 1082, both the terms of the legislation itself and its legislative history explained that exceptions would be available to ensure that SNFs could justify their reasonable costs. 42 U.S.C. § 1395yy(b); Staff of Senate Comm. on Finance, 98th Cong., 2d Sess., Explanation of Provisions Approved by the Committee on March 21, 1984 at 948 (Comm. Print 1984). As explained in Section I.B.2., *infra*, Congress made similar statements when the Secretary was given general authority to promulgate cost limits in 1972.

"new provider" criteria. *Id.* § 413.30(e) (1991). Similarly, under the regulations, hospitals may obtain exceptions for atypical services, extraordinary circumstances, geographic location, medical education programs, more intensive routine care, essential community hospital status, unusual labor cost, or changes in case mix. The only regulatory exceptions available to SNFs, on the other hand, are for atypical services, extraordinary circumstances, geographic location, and unusual labor cost. *Id.* § 413.30(f) (1991).

Equally as important, the exemptions and exceptions available to SNFs are extremely narrow or only apply to certain limited categories of costs. For example, the "extraordinary circumstances" exception only applies to events such as "strikes, fire, earthquake, [or] flood." *Id.* § 413.30(f)(2). The "geographic location" exception only allows upward revision of the cost limits where a provider is located in an area (such as a resort) with a routinely fluctuating population, and then only if a state agency makes certain findings concerning the supply of services in that area. *Id.* § 413.30(f)(3). None of the SNF cost limit exceptions covers situations where the Secretary's methodology for computing the cost limits does not account for local circumstances or contains a "formulaic" defect (*e.g.*, the use of an improper index or erroneous data) that has systemic implications or adversely affects individual providers.

SUMMARY OF ARGUMENT

Medicare providers paid under a reasonable cost system are entitled to retroactive corrective adjustments whenever the Secretary's methods of determining reasonable costs produce an inadequate or excessive result. 42 U.S.C. § 1395x(v)(1)(A)(ii) (1988 & Supp. 1990) ("clause (ii)"). As the plain language of clause (ii) reflects, these adjustments are substantive in nature, and are designed to effectuate the Medicare statute's mandate that all reasonable costs be reimbursed. *See Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 209-11 (1988).

Contrary to the Secretary's position in this and other cases, neither the "book balancing" regulations at 42 C.F.R. § 413.60-.64 nor the narrow regulatory exceptions to the cost limits at 42 C.F.R. § 413.30 implement clause (ii). The book balancing regulations do not provide for any substantive methodological adjustment to reimbursement. Similarly, the cost limit exceptions provide only limited adjustments to account for specified deficiencies in a single method, whereas the statute requires adjustments where *any* of the "methods" produce an inadequate result.

In limited contexts, the Secretary has effectively admitted that retroactive corrective adjustments are necessary to implement the statutory mandate of reasonable cost reimbursement. For example, the Secretary has disavowed his intention to enforce conclusive limits on certain health maintenance organizations in light of judicial decisions requiring a "retroactive corrective adjustment." He has also provided individual SNFs with an opportunity to prove their costs of implementing OBRA 1987 are reasonable even if those costs exceed his estimates.

Likewise, substantive retroactive corrective adjustments do not violate *Georgetown*'s prohibition against retroactive rulemaking, because such adjustments would take the form of adjudication rather than rulemaking. Further, such adjustments do not violate *Georgetown* because, as the statute makes clear, they are made to "aggregate reimbursement" rather than to the regulatory "methods" themselves.

As a practical matter, substantive retroactive corrective adjustments are necessary because of the inexact and evolving nature of ratesetting. The ratesetting process constantly must address changing federal, state, and local legal and business conditions. In many cases, no historical cost data exist from which to adjust reimbursement rates, and the Secretary must make reasonable estimates and assumptions based on the best available information to project reasonable costs on a prospective basis (*i.e.*, before adequate cost data are avail-

able). By the same token, however, the imperfection and imprecision of this process mean that retoractive corrective adjustments are necessary in order both to correct errors in estimates and assumptions and to recognize that individual providers may warrant exceptions to those estimates and assumptions.

Finally, recognition of substantive retroactive corrective adjustments by the Court would not result in numerous clause (ii) cases being filed in federal court. As a practical and jurisdictional matter, those cases must involve major reimbursement deficiencies in order to be cost-effective; the lack of a substantial number of such cases in the 27-year history of the Medicare statute bears this out. Indeed, recognition of a substantive right under clause (ii) would promote more efficient resolution of reimbursement disputes than at present.

ARGUMENT

I. CLAUSE (ii) OF 42 U.S.C. § 1395x(v)(1)(A) REQUIRES SUBSTANTIVE RETROACTIVE CORRECTIVE ADJUSTMENTS TO AN INDIVIDUAL PROVIDER'S REIMBURSEMMENT WHENEVER THE AMOUNT OF REIMBURSEMENT PRODUCED BY THE SECRETARY'S REGULATORY METHODS FAILS TO COVER A PROVIDER'S ACTUAL REASONABLE COSTS.

At bottom, this case is about whether the Secretary's duty to reimburse Medicare providers for their full reasonable costs is qualified or absolute. The language of clause (ii) and the Secretary's own recent conduct make clear that the duty is absolute and is not satisfied by mere "book balancing" adjustments or narrow cost limit exceptions. Instead, clause (ii) requires substantive adjustments to individual providers' reimbursement where the regulatory methods produce an inadequate result. Such adjustments need not alter the methods themselves, however, and therefore do not violate *Georgetown*'s prohibition against retroactive rulemaking.

A. The Plain Language Of Clause (ii) Requires Substantive Adjustments To Reimbursement To Account For Reasonable Costs.

"Reasonable costs" under the Medicare statute are those costs "actually incurred, excluding therefrom any part of incurred cost found to be unnecessary in the efficient delivery of health services." 42 U.S.C. § 1395x(v)(1)(A). The statute authorizes the Secretary to develop the "method or methods" to be used to "determine" such costs. The statutory definition of reasonable costs makes clear, however, that the Secretary's authority to promulgate regulations establishing the methods for identifying such costs (including potential methods such as cost limits) does not diminish his statutory duty to reimburse reasonable costs in full.

The final sentence of 42 U.S.C. § 1395x(v)(1)(A) confirms this duty by establishing mandatory minimum standards that the Secretary's regulations must meet. Clause (i) essentially prohibits regulatory methods that would result in "cross-subsidization" of Medicare services, *i.e.*, payment for the reasonable costs of those services from other sources as a result of "cost-shifting." In other words, clause (i) confirms the Secretary's duty to reimburse Medicare reasonable costs *in full*.

Clause (ii) requires "suitable retroactive corrective adjustments" where the "methods of determining costs" yield either "inadequate or excessive" reimbursement to a provider. This requirement creates a substantive right that enables health care providers to enforce, through case-by-case adjudication, the Secretary's duty to reimburse reasonable costs in full. *Georgetown*, 488 U.S. at 209-10. The language of clause (ii) clearly contemplates "substantive" adjustments to a provider's reimbursement. First, clause (ii) on its face requires adjustments to the "reimbursement produced by the methods." In other words, the Secretary's regulatory methods for determining reasonable costs are always subject to his duty to reimburse an individual provider's reasonable costs in full even where the methods are otherwise valid. *Regents*

of Univ. of Cal. v. Heckler, 771 F.2d 1182, 1189 (9th Cir. 1985). Second, the use of the terms "inadequate" and "excessive" to modify "reimbursement" and the description of adjustments as "corrective" both suggest adjustments for substantive reimbursement disparities.

B. Neither The Secretary's "Book Balancing" Regulations Nor The Secretary's Exceptions To The Cost Limits Satisfy The Requirement For Retroactive Corrective Adjustments Under Clause (ii).

Historically, the Secretary has posited two principal alternative theories of how he has satisfied his duties under clause (ii): the "book balancing" regulations at 42 C.F.R. § 413.60-.64; and the "cost limit exceptions" at 42 C.F.R. § 413.30(f). Neither set of regulations fully satisfies the mandate of clause (ii), however. Moreover, the Secretary's actions with respect to reimbursement of SNFs and other types of providers belie his arguments.

1. *The "book balancing" regulations do not satisfy the Secretary's duties under clause (ii).*

Under the reasonable cost reimbursement system, the Medicare program periodically pays providers an "interim" rate during the course of a cost year. These interim rates are based on the provider's actual reasonable costs in the past. 42 C.F.R. § 413.64(a) (1991). This system allows providers to obtain sufficient cash flow to sustain their Medicare operations, while avoiding the continual need to submit documentation of costs (and the corresponding burden on the Secretary to process cost claims). At the end of the cost period, the provider then submits a cost report, which the Secretary audits in accordance with the regulatory methods for determining reasonable costs. Once the Secretary determines the total amount to be reimbursed, this amount is then reconciled (upwards or downwards) with the total interim payments. *Id.* §§ 413.60(c), 413.64(f) (1991). In short, the year-end reconciliation is not a "method" of reimbursement because it does not make any substantive adjustment to the provider's reasonable cost reimbursement. Rather, it is merely a payment procedure designed to minimize administrative burdens for the Medicare program while ensuring adequate cash flow for its providers.

Aside from the actual failure of the book balancing regulations to produce the substantive adjustments required under clause (ii), the text and structure of the Medicare statute further confirm that the book balancing regulations do not implement clause (ii). Even if the interim rate could be deemed a "reasonable cost" method, clause (ii) requires adjustments when *any* of the "methods" produce inadequate reimbursement. If clause (ii) were fully implemented by the book balancing regulations, the statute's use of the plural would not be given full effect because *only* the single payment "method" of interim payments could produce an inadequate or excessive result.

In addition, the book balancing regulations are authorized under a separate section of the Medicare statute which describes the mechanics of payment and requires "adjustments on account of previously made overpayments or underpayments." 42 U.S.C. § 1395g(a) (1988). The book balancing regulations' reconciliation process accounts for these "overpayments and underpayments" rather than for "inadequate or excessive" reimbursement.

Finally, *Georgetown* did not hold or imply that the book balancing regulations meet the Secretary's duty to provide for retroactive corrective adjustments under clause (ii). Instead, the Court expressly recognized on several occasions that clause (ii) calls for substantive adjustments to an individual provider's reimbursement whenever the methods produce an inadequate result. *See* 488 U.S. at 209-11. The Court's only discussion of the book-balancing regulations was not a ruling on what clause (ii) requires, but rather was part of a broader rejection of the Secretary's position that clause (ii) permits retroactive rulemaking. *See id.* at 211 & n.2. The issue of what clause (ii) requires is squarely before the Court in *this* case.

2. *The cost limit exceptions do not fully implement clause (ii).*

The Secretary's brief in response to the petition for certiorari suggests that he also believes that the cost limit exceptions satisfy his duties with respect to clause (ii). That position again overlooks the narrow coverage of the exceptions, the language of clause (ii), and the legislative history of the cost limits.

Clause (ii) requires retroactive corrective adjustments whenever *any* of the "methods" of determining reasonable costs results in inadequate reimbursement. It does not merely authorize special rules when the method in question is a cost limit. *See Regents*, 771 F.2d at 1189. The cost limit exceptions, on the other hand, are narrowly tailored, particularly as they apply to SNFs. The Secretary's argument that the exceptions implement clause (ii) is therefore inconsistent with the use of the plural term "methods," because the narrow exceptions clearly do not provide for adjustments where the cost limits—or other reimbursement "methods"—result in inadequate aggregate reimbursement and the nature of the deficiency does not fall neatly within one of the enumerated exceptions.[5] As the Eleventh Circuit noted in *Medical Center Hospital v. Bowen*, 839 F.2d 1504, 1511 (11th Cir. 1988), "We can imagine myriad situations where resort to the Secretary's exceptions process would not result in the provider receiving the full reimbursement to which it is entitled under the statute." In short, clause (ii) requires adjustments with respect to inadequate reimbursement regardless of the reimbursement method at fault, but the cost limit exceptions clearly do not provide such relief.

Moreover, as petitioners explain in greater detail, the legislative history to congressional authorization of cost limits clearly indicates that such limits were designed to be purely presumptive and that providers would be able

[5] An example of a method other than the cost limits which may inadequately reimburse individual SNFs, even though such method may not be invalid across-the-board, is discussed *infra* in Part II.B.

to obtain relief from the limits on the basis of evidence of reasonable costs. *See* S. Rep. 1230, 92d Cong., 2d Sess. 188-89 (1972); H.R. Rep. No. 231, 92d Cong., 1st Sess. 83-85 (1971), *reprinted in* 1972 U.S.C.C.A.N. 4989, 5070-71. Even the Secretary recognized the imperfect nature of the cost limits from their outset. *See* 39 Fed. Reg. 20,164 (Jun. 6, 1974) (noting that the proposed limits were not as "refined" or "advanced" as those that might be possible in the future).[6] One additional point bears note, however: insofar as the substantive adjustment requirements of clause (ii) predated the 1972 authorization for cost limits, the more rational construction of the cost limit exceptions is that they merely define some circumstances under which those limits do not apply. They are not the sole or exclusive means of implementing clause (ii).[7]

[6] Moreover, the Secretary argues that the cost limits are conclusive as to costs in excess of the limits except under the narrow exceptions in the regulations, while in practice he treats the cost limits as merely being broadly presumptive when costs are below the limits. In other words, a provider having costs below the limits is not simply paid these costs, but rather the Secretary remains free to make further disallowances if he finds that the costs are not reasonable, necessary, proper, or related to patient care. *See* 42 C.F.R. § 413.9 (1991). Why the Secretary can make wide-ranging determinations of "reasonableness" as to the costs of providers below the limits, while he cannot do so for provider costs above the limits (or in excess of other methods) seems inexplicable.

[7] The Secretary's argument concerning the meaning of clause (ii) is clearly inconsistent. On the one hand, he seems to suggest that, before 1972, clause (ii) required only book balancing regulations to reconcile interim and final payments. On the other hand, he appears to contend that, even though clause (ii) was not altered or amended in any way, it suddenly required substantive corrective adjustments after 1972 to payments produced by the rate methods—but only insofar as they involved certain narrow exceptions to the cost limits method. There is no statutory basis or legislative history to support this contention.

3. *The Secretary's recent administration of the reasonable cost reimbursement system for health maintenance organizations and SNFs demonstrates his acknowledgment of his duty to provide substantive retroactive corrective adjustments.*

Two recent examples of the Secretary's administration of Medicare's reasonable cost reimbursement system demonstrate that he recognizes that the duty to provide retroactive corrective adjustments is not limited to either book balancing or cost limit exceptions, but rather involves substantive adjustments to reimbursement.

First, in 1989 (after *Georgetown*) the Secretary issued a formal ruling applicable to reimbursement of Medicare cost-based health maintenance organizations ("HMOs").[8] Similar to other reasonable cost providers, cost-based HMOs are entitled to "appropriate retroactive corrective adjustment[s] at the end of each contract year so as to assure that such organization[s are] paid for the reasonable cost actually incurred (excluding any part of incurred cost found to be unnecessary in the efficient delivery of health services) . . . ." *Id.* § 1395mm(h)(3). In 1985, however, the Secretary issued a rule that applied the 95 percent per capita rate normally applicable to risk-based HMOs as "an absolute limitation on the total amount payable" to cost-based HMOs. 42 C.F.R. § 417.532(a)(3) (1991).

Four years later, the Secretary issued a policy statement disavowing his intention to enforce § 417.532. In that ruling, the Secretary specifically acknowledged the identical meanings of the "retroactive corrective adjustment" language in clause (ii) and the HMO statute, and explicitly based his decision not to enforce the regulation on the clause (ii) decisions in *Medical Center Hospital* and *Regents*. HCFA Ruling 89-2 (Oct. 31, 1989), *reprinted in* [1990 Transfer Binder] Medicare & Medicaid Guide (CCH) ¶ 38,237. The Secretary disavowed the regulation because it "impose[d] an absolute limit on reimbursement without an exceptions process or criteria for evaluating whether costs in excess of the limit were in fact reasonable." *Id.*

[8] Most HMOs are reimbursed under Medicare through "risk" contracts pursuant to which the HMO receives a per capita rate for each Medicare beneficiary based on 95 percent of the average per capita costs of Medicare beneficiaries. These HMOs bear the risk that the cost of caring for that beneficiary may exceed the per capita amount. Other HMOs may enter into "reasonable cost reimbursement contracts" with the Secretary. *See* 42 U.S.C. § 1395mm (1988).

The Secretary may seek to distinguish his action with respect to the HMO regulation from his treatment of the cost limits for hospitals and SNFs on the ground that the latter provide some minimal exceptions and therefore do not constitute an absolute limit. As the preceding section demonstrated, however, the Secretary's cost limit exceptions are not sufficient to meet his more general duties under clause (ii). Moreover, the Secretary's attempted distinction must be seen as purely self-serving, because HCFA Rulings are designed to "promote consistency in interpretation of policy and adjudication of disputes." HCFA Ruling 92-1 (Aug. 1992), *reprinted in* 5 Medicare & Medicare Guide (CCH) ¶ 40,769. It is difficult to imagine how a ruling that relies on clause (ii) cases to create broad opportunities for retroactive corrective adjustments in the HMO context can be "consistent" with the refusal to utilize a similar principle for hospitals and SNFs, especially where the cases that generated HCFA Ruling 89-2 arose in the hospital context.

The second recent example of the Secretary's partial recognition of his clause (ii) duty arose following implementation of OBRA 1987's nursing home reforms. Congress recognized that existing SNFs would have to incur various new costs in order to provide the enhanced quality of care and quality of life for nursing home resi-

dents that OBRA 1987 envisions. *See* H.R. Rep. No. 391(II), 100th Cong., 1st Sess. 937 (1987), *reprinted in* 1987 U.S.C.C.A.N. 2313-1, 2313-554. Accordingly, Congress amended the Medicare statute to clarify that these "OBRA costs" must be reimbursed under the reasonable cost system. 42 U.S.C. § 1395x(v)(1)(E).

A year *after* the effective date of OBRA 1987, the Secretary revised the SNF cost limits to provide an "add-on" increase to the limits to account for SNFs' OBRA costs.[9] Although the Secretary recognized that he "did not have data available to establish a precise add-on factor to the limits that would compensate SNFs for these new costs," he nevertheless computed a nationwide add-on to the cost limits based on state Medicaid programs' proposed reimbursement for OBRA costs.[10] 56 Fed. Reg. 13,317, 13,318, 13,322-23 (Apr. 1, 1991). Significantly, however, the Secretary recognized that the actual amount of additional OBRA costs would vary from facility to facility depending on individual circumstances and applicable state law, and therefore established a mechanism —consistent with clause (ii)—to enable SNFs to recover their full reasonable OBRA costs:

> [W]e would provide financial relief for those costs by *adjusting* cost limits. An *adjustment* to the cost limit will be made to the extent the costs in excess of the limit are reasonable, actually incurred in the process of implementing the additional requirements,

[9] In Part II.A., *infra*, we explain the deficiencies of the Secretary's OBRA 1987 add-on methodology which necessitate a retroactive corrective adjustment allowing substantive modifications to reimbursement.

[10] OBRA 1987's reforms apply to NFs under the Medicaid program as well as under Medicare. OBRA 1987 required states to submit amendments to their state Medicaid plans that set forth the additional reimbursement amounts necessary to cover the OBRA costs of an economically and efficiently operated NF (which does not necessarily include all NFs). OBRA 1987, § 4211(b)(2), 101 Stat. at 1330-203.

> separately identified by the provider, and verified by the intermediary.

Id. at 13,318 (emphasis added). The Secretary continued this adjustment process in his most recent update of the SNF cost limits. *See* 57 Fed. Reg. 46,177, 46,181 (Oct. 7, 1992).

The Secretary's implementation of OBRA 1987 further belies his argument that the regulatory cost limit exceptions satisfy his duties under clause (ii). SNF cost limit exceptions existed throughout the implementation of OBRA, yet the Secretary established an additional mechanism for "adjustments" where individual SNFs can show that they incurred reasonable costs in excess of the nationwide OBRA cost add-on. These are precisely the type of case-by-case retroactive corrective adjustments that the petitioners seek. The Secretary's implementation of OBRA 1987 therefore confirms that he recognizes his duty to make individualized, substantive retroactive corrective adjustments whenever a method of determining reasonable cost—including cost limits—produces an inadequate result.

C. The Retroactive Corrective Adjustments Sought By Petitioners Are Not Inconsistent With *Georgetown*'s Prohibition Against Retroactive Rulemaking.

Petitioners' efforts to secure retroactive corrective adjustments do not resemble the actions of the Secretary which were struck down as retroactive rulemaking in *Georgetown*. Nor are such adjustments inconsistent, standing alone, with the general presumption against retroactive rulemaking.

In *Georgetown*, the district court invalidated the Secretary's 1981 cost limit schedule as a procedurally invalid rule under the Administrative Procedure Act ("APA"), 5 U.S.C. § 551 *et seq.* (1988 & Supp. 1990). In 1984, following that decision, the Secretary issued a new cost limit schedule, identical to the 1981 schedule and with an effective date of 1981, and proceeded to recoup sums previously paid as a result of the district court's earlier rul-

ing invalidating the 1981 rule. *See* 488 U.S. at 206-207. In short, the challenged action of the Secretary in *Georgetown* indisputably involved retroactive rulemaking.

By contrast, petitioners seek only aggregate reimbursement adjustments for individual hospitals, after a hearing at which they would have an opportunity to demonstrate that their costs during a historic time period were reasonable. These hearings are not rulemaking, but rather are adjudications—a "form of administrative action where retroactivity is not only permissible but standard." *Id.* at 221 (Scalia, J., concurring). The latter are permitted under *Georgetown*; the former are not. *See Mt. Diablo Hosp. v. Sullivan*, 963 F.2d 1175, 1182 (9th Cir. 1992), *petition for cert. pending*, 61 U.S.L.W. 3356 (U.S.) (No. 92-720).

The court below believed that relief in excess of the cost limits would amount to a retroactive change in the methods for determining reimbursement, because petitioners' evidence included an examination of the deficiency of those methods. *Good Samaritan Hosp. v. Sullivan*, 952 F.2d 1017, 1027 (8th Cir. 1991). That reasoning overlooks the fact that, in order to receive an adjustment, petitioners would need to demonstrate the reasonableness of their costs in excess of the cost limits. Although this showing might involve an examination of the methodological deficiencies of the cost limits, it is not necessary coterminous with such a review.[11] Moreover, nothing on the face of clause (ii) requires that a retroactive corrective adjustment must result in a modification of the methods themselves. Instead, such adjustments need only modify the "aggregate reimbursement" resulting from those methods.

[11] For this reason, the retroactive corrective adjustment provisions do not afford a "second bite at the apple," in the sense that the District of Columbia Circuit found in *Hennepin County v. Sullivan*, 883 F.2d 85, 92 (D.C. Cir. 1989), *cert. denied*, 493 U.S. 1043 (1990). In *Hennepin*, the providers failed to meet their burden of proof as to a facially applicable cost limit exception for medical education costs. 883 F.2d at 91. After this failure, the providers sought a general exception under clause (ii) as to "the same claim under precisely the same standard that had already proven unsuccessful." *Id.* at 92. Here, by contrast, there is no cost limits exception applicable to petitioners' claims.

Finally, the Secretary's implementation of the OBRA cost add-on for SNFs confirms that his "retroactive rulemaking" argument is strictly one of convenience. As described above, the Secretary specifically provided (four days before the Court granted certiorari in this case) for retroactive corrective adjustments where individual SNFs can demonstrate that their OBRA costs exceed the OBRA cost add-on to the cost limits. *See* 57 Fed. Reg. at 46,181. Those adjustments are functionally indistinguishable from what petitioners seek.

II. SUBSTANTIVE RETROACTIVE CORRECTIVE ADJUSTMENTS ARE NECESSARY TO IMPLEMENT THE SECRETARY'S DUTY TO REIMBURSE SNFS FOR THEIR FULL REASONABLE COSTS IN LIGHT OF THE EVOLVING REGULATORY ENVIRONMENT AND WOULD PROMOTE EFFICIENCY IN THE ADJUDICATION OF SUCH REIMBURSEMENT DETERMINATIONS.

When Congress originally authorized the Secretary to establish Medicare cost limits in 1972, it realized that perfection or absolute equity would not be possible when prospective limits were applied to classes of providers. In this vein, Congress noted that costs can and do differ among institutions for a variety of legitimate reasons that may be unrelated to inefficiency. It also explicitly acknowledged that the initial ceilings would necessarily be "imprecise," that available data "will often be less than perfectly reliable," that the precision of the limits is dependent upon the ability to distinguish "excess costs . . . from the provision of higher quality or intensity of care," and that it would be difficult to set limits with regard to costs that vary with quality and intensity of care. S. Rep. No. 1230, 92d Cong., 2d Sess. 187-89 (1972); H.R. Rep. No. 231, 92d Cong., 1st Sess. 82-84 (1971), *reprinted in* 1972 U.S.C.C.A.N. 4989, 5069-71.

Given these circumstances, it is hardly surprising that Congress denominated the limits "presumptive" (rather than "conclusive") and explained that exceptions would be available based on evidence of need. *Id.* The Secretary, too, conceded that the initial cost limits were not "refined" or "advanced." 39 Fed Reg at 20,164.

Although there have undoubtedly been some advances in data collection and analysis, it is clear that developing annual cost limits—or utilizing other methods to determine reasonable cost—remains an imperfect science. Obviously, the fact that the limits are not entirely fair or accurate for each and every affected provider does not mean that they are unlawful. Under an "arbitrary and capricious" standard, the Secretary's actions are accorded some deference. Conversely, however, the fact that the limits need not be completely precise or equitable means that, in order to give effect to the statutory mandate of full reasonable cost reimbursement, there must be sufficient flexibility to recognize exceptions when the provider can establish that its excess costs are nonetheless reasonable. Such adjustments would also promote the efficient administrative and judicial adjudication of Medicare reimbursement disputes.

A. The Secretary's Implementation Of The SNF Cost Limits Demonstrates The Need For Retroactive Cost Adjustments To Enable Individual Providers To Receive Their Full Reasonable Costs.

The Secretary's practices with respect to the SNF routine cost limits illustrate the imperfect nature of those limits, and the corresponding need for substantive adjustments to individual providers' reimbursement in order to implement the statutory mandate.

The Secretary first issued SNF cost limits in 1979, and (with minor variations) has followed the same basic methodology for computing those limits since that time.[12]

[12] *See* 57 Fed. Reg. at 47,177; 56 Fed. Reg. at 13,317; 51 Fed. Reg. 11,253, 11,255-56 (Apr. 1, 1986); 47 Fed. Reg. 42,894, 42,898-99 (Sept. 29, 1982); 46 Fed. Reg. 48,026, 48,029 (Sept. 30, 1981); 45 Fed. Reg. 58,699, 58,703 (Sept. 4, 1980); 44 Fed. Reg. 51,542, 51,545-46 (Aug. 31, 1979).

To compute the limits, the Secretary (1) gathers cost data from SNF cost reports during a common base period, (2) trends that data forward to a common endpoint using a specially developed "market basket" index, (3) determines the labor- and non-labor related portions of each SNF's adjusted costs using data from the market basket index, (4) calculates limits for the labor- and non-labor costs as a percentage of SNFs' mean adjusted costs, (5) adjusts the labor-related limit using a hospital wage index (*i.e.*, the same wage index petitioners challenge) to account for regional variations in labor costs, (6) adds the adjusted labor-related limit to the non-labor limit, and (7) adds any "add-ons" to arrive at the total cost limit. *See, e.g.*, 57 Fed. Reg. at 46,179-81.

Numerous assumptions and estimates are implicit in this methodology. Among other things, the methodology assumes that: (1) the *historic* cost report data accurately represent costs that SNFs *currently* incur; (2) the market basket index is accurate; (3) the *hospital* wage index accurately reflects regional variations in *SNF* labor costs; and (4) the selected percentages of the mean accurately reflect SNFs' reasonable costs. Such assumptions have not always been borne out by experience. Although that fact alone is not necessarily sufficient to invalidate the cost limits as a whole, it nevertheless demonstrates that the cost limits are inexact in nature. In such an inexact system, some sort of additional mechanism is necessary to allow SNFs to obtain reimbursement for their full reasonable costs under 42 U.S.C. § 1395x(v)(1)(A).

For example, the Secretary did not use an updated cost report data base to set the limits between 1982-1986 or 1986-1991, and used 1982 cost report data to calculate the 1986 limits. 51 Fed. Reg. at 11,255. The Secretary's failure to "rebase" the limits more frequently ultimately led Congress to enact a provision as part of the Omnibus Budget Reconciliation of 1989 ("OBRA 1989") which required the Secretary to update the limits using more

recent cost report data. OBRA 1989, § 6024, P.L. No. 101-239, 103 Stat. 2106, 2167. The Secretary failed to implement this provision, however, resulting in further "rebasing" requirements in Section 4008(e) of the Omnibus Budget Reconciliation Act of 1990, P.L. 101-508, 104 Stat. 1388, 1388-45. *See* H.R. Conf. Rep. No. 964, 101st Cong., 2d Sess. 706 (1990), *reprinted in* 1990 U.S.C.C.A.N. 2374, 2411.

More recently, the Secretary's calculation of "OBRA cost" and other add-ons to the cost limits illustrates the need for substantive retroactive corrective adjustments. As noted previously, the Secretary used data contained in state Medicaid plans to determine the Medicare OBRA cost add-on. The Secretary's use of such data raises numerous methodological problems. First, at the time of the cost limit adjustment (which itself was nearly six months after the effective date of OBRA 1987), the Secretary had approved state plans from only 36 states. *See* 56 Fed. Reg. at 13,322. Second, as the Court recognized in *Wilder v. Virginia Hospital Ass'n*, 496 U.S. 498, 507-08 (1990), the Secretary does not generally engage in a detailed review of state Medicaid plans to determine the substantive adequacy of the states' reimbursement methodology or rates. Third, under 42 U.S.C. § 1396a (a)(13)(A), which sets forth the federal requirements for reimbursement of hospitals and SNFs under Medicaid, states are not required to reimburse providers on a reasonable cost basis. *See Virginia Hosp. Ass'n*, 496 U.S. at 505-07. Indeed, many states employ prospective ratesetting methodologies to pay nursing facilities, which need only pay the allowable costs of "efficiently and economically operated" providers *as defined by the state*. *See, e.g., West Virginia Univ. Hosps. v. Casey*, 885 F.2d 11, 26 (3d Cir. 1989), *cert. denied*, 496 U.S. 936 (1990).

States' OBRA 1987 cost adjustments therefore did not necessarily reflect the full reasonable costs to nursing homes of complying with OBRA 1987, and varied greatly from state to state depending, in part, on the pre-existing requirements that had been applicable in the state. In

sum, the Secretary used "data" that was imprecise at best, and irrelevant at worst, to compute the OBRA 1987 add-on to the SNF cost limits. As the Secretary apparently recognized, substantive retroactive corrective adjustments were therefore necessary to account for the discrepancies between the data and the subsequent actual cost experience of SNFs in implementing OBRA 1987.

Similarly, the Secretary's most recent revision of the cost limits included an add-on to account for SNFs' costs to comply with recent rules issued by the Occupational Health and Safety Administration ("OSHA") to minimize occupational exposure to bloodborne pathogens such as the AIDS virus. *See* 57 Fed. Reg. at 46,181. With respect to that add-on, the Secretary conducted no independent analysis of the likely costs, but instead relied solely upon the "technical data supporting the OSHA rule." *Id.* Again, the Secretary recognized the inexact nature of the cost estimates, and now permits individual SNFs to offer evidence that their costs in excess of the OSHA add-on are nevertheless reasonable. *Id.*

These examples underscore how ratesetting is a dynamic, inexact process, which relies on assumptions and frequently must account for novel changes in federal law and local conditions for which there may be no historic data to make reliable estimates. In light of the nature of ratesetting, the Secretary is certainly entitled to (and receives, through the APA's "arbitrary and capricious" standard) deference in his efforts to respond to those changing conditions. At the same time, however, the inexact nature of the process necessitates a retrospective mechanism to adjust for erroneous assumptions or the failure of the Secretary to recognize or address changing conditions, in light of the Medicare program's statutory mandate that all reasonable costs be reimbursed.

B. Variations In State Regulatory Practices Create Disparities That Necessitate Retroactive Cost Adjustments For Individual Providers.

Changes in federal mandates are not the only situations requiring retroactive corrective adjustments. Health care

providers are also subject to significant regulation under state law, which may impose additional costs in and of themselves (*e.g.*, insurance premiums) or may affect the costs resulting from federal mandates.[13]

Moreover, state mandates may affect the adequacy of the reimbursement resulting from "methods" other than simply the cost limits. For example, under the Medicare statute, a nursing home may have less than all of its beds participate in the Medicare program as a "distinct part" SNF. *See* 42 U.S.C. § 1395i-3(a) (1988 & Supp. 1990). SNFs receive per diem reimbursement based on the average cost for all patients (Medicare and non-Medicare) within the distinct part. Distinct part participation enables a facility to allocate its resources for caring for high acuity, Medicare SNF patients in one portion of the facility, and thereby to account more accurately for the actual reasonable costs of caring for those Medicare patients.

A few states' nursing home licensure laws require nursing homes to have *all* of their beds certified for Medicare participation. The effect of this provision is that it includes the comparatively low cost of caring for non-Medicare patients, whose needs are not as acute, in the calculation of average cost for purposes of Medicare reimbursement. This may reduce the average cost (and thereby the per diem Medicare reimbursement) of the SNF, potentially resulting in reimbursement of less than all of the actual reasonable costs of caring for higher acuity Medicare patients.

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[13] An example of this latter situation occurred in the context of OBRA 1987, when a number of states argued that their state licensure laws already imposed many of the same duties as OBRA 1987, and that nursing homes therefore incurred no additional costs as a result of OBRA 1987. Other states, by contrast, had previously adopted comparatively few of OBRA 1987's requirements, and therefore provided more substantial OBRA cost adjustments in their Medicaid rates.

Without retroactive corrective adjustments, a SNF would be left to challenge the "average cost" method of determining per diem reimbursement as arbitrary and capricious. On a nationwide basis, however, the average cost method may well represent a reasonable means to apportion costs between Medicare and non-Medicare patients, particularly since almost all states permit distinct part participation. Notwithstanding that fact, the average cost methodology may not reimburse the reasonable costs of treating Medicare patients for SNFs in states that prohibit Medicare distinct part participation.

Obviously, the Secretary cannot practically be expected to monitor all laws in 50 states to determine their potential effect on the Medicare reimbursement of individual providers. He can, however, be held accountable where individual providers bring such situations (and their effect on reimbursement of reasonable costs) to his attention. Substantive retroactive corrective adjustments reflect the cost effects of state and local laws, so that Medicare providers may be given the opportunity to receive their full reasonable costs as 42 U.S.C. § 1395x(v)(1)(A) requires.

C. Recognizing The Requirement For Retroactive Corrective Adjustments Would Not Open The Floodgates To Federal Court Review Of Individual Medicare Rate Disputes But, Instead, Would Promote The Efficient Resolution Of Such Disputes.

Despite longstanding holdings by most federal courts of appeals that clause (ii) requires substantive retroactive corrective adjustments, relatively few clause (ii) cases have been adjudicated. Confirming such a right in this case will not likely change that practice, in light of the jurisdictional and practical difficulties of such cases. To the contrary, a firmly established right to adjustments under clause (ii) would promote efficient use of judicial resources by shifting the adjudication of such disputes to the administrative arena in the first instance.

1. *Providers have invoked clause (ii) prudently.*

Since the enactment of the Medicare program in 1965, federal law has, through clause (ii) and its predecessor provision,[14] contained a requirement that there be suitable retroactive corrective adjustments. This requirement has remained unchanged, even when Congress first empowered the Secretary to develop presumptive cost limits in 1972. Despite the longevity of clause (ii)'s existence (27 years), the length of time that such cost limits have been authorized (20 years) and utilized (18 years), and the fact that most federal courts have interpreted clause (ii) to require substantive "reasonable cost" adjustments for individual providers rather than mere book balancing, there have been relatively few cases in which Medicare providers have invoked clause (ii) to seek individualized rate adjustments.[15] There are several compelling reasons why this is unlikely to change if this Court were to adopt the approach urged by petitioners.

First, a provider may not seek review through the Provider Reimbursement Review Board ("PRRB") and to the courts unless the amount of Medicare reimbursement in controversy for each fiscal year under appeal is at least $10,000. 42 U.S.C. § 1395oo(a)(2) (1988); 42

[14] 42 U.S.C. § 1395x(v)(1)(B) (1964 & Supp. 1965-69).

[15] The first court of appeals decision to interpret the clause (ii) requirement was *Kingsbrook Jewish Medical Center v. Richardson*, 486 F.2d 663 (2d Cir. 1973), and it held that individual retroactive corrective adjustments were mandated. Our research shows that, in a period spanning almost three decades, reported federal court decisions that have discussed or even cited clause (ii) or its predecessor provision apparently number less than 100 opinions. Moreover, a number of those cases involved circumstances in which clause (ii) was not directly at issue but was cited only for illustrative purposes. Similarly, some of the decisions represented the same case at different stages of review and appeal, and others entailed litigation in which the Secretary invoked clause (ii) as a basis for making adjustments to deny reimbursement of certain costs. Thus, it is evident that, historically, providers have been judicious in their use of clause (ii) to seek individual retroactive corrective adjustments.

C.F.R. §§ 405.1835(a)(3), 405.1839(a) (1991). PRRB appeals of common questions of law or fact by groups of providers must aggregate at least $50,000. 42 U.S.C. § 1395oo(b) (1988); 42 C.F.R. § 405.1839(b) (1991).

Second, the expense of undertaking clause (ii) challenges is inevitably considerable. Invariably, the sums at issue are significantly greater than the jurisdictional threshold amounts because it is extremely costly to develop and litigate clause (ii) cases. The burden of proof in these cases must be shouldered by the provider; it must prove that the method(s) do not reimburse its reasonable costs, and what those reasonable costs are. Normally, this requires the retention and use of experts to review and prepare detailed and extensive statistical and accounting evidence to try to demonstrate that a provider's costs are in fact reasonable. Typically, this evidence takes the form of data to establish that the provider's costs are reasonable both individually (*i.e.*, as to that specific provider) and comparatively (*i.e.*, as to other providers which are similarly situated). As part of this process, the provider will also ordinarily go beyond such showings not only to depict that the method(s) of reasonable cost determination have resulted in inadequate reimbursement but also to explain why they have proven insufficient. Additionaliy, the provider generally uses legal counsel to present factual documentation in the form of legal arguments and briefs. As a practical consequence, providers have to have substantial amounts at stake to initiate these cases, and have not done so lightly.

Finally, the cases themselves are time-consuming. The time lag between the relevant rate period and the results of the fiscal intermediary's audit may itself be several years. Thereafter, the provider must seek PRRB and/or judicial review, which frequently includes judicial remand of the case for hearing before the PRRB.[16]

[16] As explained, *infra*, at Section II.C.2, a clear directive by this Court that the PRRB may entertain clause (ii) cases in the first instance would aid efficiency and economy by reducing the effects of administrative and judicial "ping-pong" in these cases.

Under such circumstances, it is hard to envision a provider launching a clause (ii) case for whimsical reasons, especially where the result that the provider is challenging may be a phenomenon that is limited in time, either because the provider's circumstances change or because the result is produced by a method or methods—such as cost limits—that are periodically revised.[17]

2. *A clause (ii) remedy through the PRRB would enhance administrative and judicial efficiency.*

As the district court's order in this case suggests, the PRRB itself is a means by which the Secretary may implement his duty to provide for individual retroactive corrective adjustments. In fact, the use of the PRRB to resolve such cases would promote legitimate objectives of administrative and judicial economy.

The Secretary's current refusal to provide for the types of individual clause (ii) adjustments sought by petitioners has actually led to additional administrative and judicial burdens. For example, the Secretary's opposition to such adjustments has often caused providers to cloak their appeals in terms of methodological challenges—that is, claims that the methods themselves are invalid as "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law . . . ." 5 U.S.C. § 706 (2)(A) (1988). These challenges may range from claims that the methods (*e.g.*, cost limits) are systemically flawed and invalid to contentions that the methods have not been lawfully promulgated via appropriate rule-

[17] The Secretary's brief in response to the petition for certiorari implies (p. 12) that, because of the size of the Medicare program, the use of individual adjustments through clause (ii) would be an administrative nightmare. The facts are that: (1) there have not been a large number of clause (ii) cases historically; (2) there is an existing administrative process which is well-equipped to handle these cases; (3) the evidentiary burden is on the provider; (4) the sums at stake in these cases may be significant for the individual providers but are minuscule in terms of overall program expenditures; and (5) the Secretary already employs an elaborate system of audits and routinely makes adjustments, including adjustments to reduce costs that are already below the limits.

making (*e.g.*, *Georgetown*).[18] Because the PRRB cannot invalidate the methods, it must authorize expedited judicial review of such challenges (42 U.S.C. § 1395oo(f)(1) (1988)) and has done so even when, as in the instant case, they are coupled with assertions that the individual providers are entitled to clause (ii) adjustments. If the provider's methodological challenge is unsuccessful in the courts, the case may still be remanded to the PRRB for a hearing on the clause (ii) claims. Such a process misallocates administrative and judicial resources.

Recognition of petitioners' statutory rights to assert clause (ii) claims would promote administrative and judicial efficiency. First, it might forestall needless methodological challenges—and the attention which courts have to pay to them—by offering the prospect of individual adjustments if warranted. Second, in any case in which a clause (ii) claim is made—regardless of whether it is or is not coupled with the methodological challenge—the PRRB could initially hear and rule upon that claim.[19] The result reached by the PRRB could mean that judicial review is never needed or is provided only after the issues have been appropriately narrowed and an administrative record has been built.

[18] There is no doubt that such methodological challenges may be undertaken and even the Secretary has conceded their permissibility. *See* Secretary's Brief in Response to the Petition for Certiorari at p. 10.

[19] Cases in which there are only methodological challenges would continue to go to court after the PRRB determined that it could not entertain the challenges. If clause (ii) claims are recognized here, however, these cases would unquestionably be fewer in number than either those which must now be reviewed by the courts or than would be filed as methodological challenges if no effective clause (ii) remedy exists.

CONCLUSION

For the foregoing reasons, the Eighth Circuit's decision should be reversed, and the case should be remanded to the PRRB in accordance with the district court's order.

Respectfully submitted,

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